UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAYCOL PRODUCTS LITIGATION	MDL No. 1431 (MJD/JGL)
This Document Relates to All Actions	Pretrial Order No. 94

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This matter is before the Court upon Plaintiffs' motion for class certification.

Background

This action involves the prescription drug, Cerivistatin, which was marketed in the United States under the brand name Baycol. Cerivistatin is a member of a class of drug known as statins, that have been routinely prescribed to lower the lipid levels of

individuals with high cholesterol, with the goal of decreasing the risk of cardiac diseases. Statins have been available since the late 1980's and have been widely prescribed.

In June 1997, the FDA approved Baycol in dosages of .02 and .03 mgs. These dosages were then launched in early 1998. In May 1999, the FDA approved Baycol in a .04 mg dose, which dose became available in June 1999. One year later, the FDA approved a .08 mg dose, which became available in August 2000. In August 2001, however, Baycol was withdrawn from the market after thirty-one deaths in the United States were linked to Baycol use. A number of adverse event reports were also submitted, suggesting a link between Baycol and diseases such as rhabdomyolysis ("rhabdo")[1], myalgia, myositis and myopathy.

After Baycol was taken off the market, thousands of lawsuits commenced throughout the country in state and federal court, asserting, *inter alia,* claims of strict liability, negligence, breach of warranty and medical monitoring. Given the number of cases filed in federal court, the Judicial Panel on Multidistrict Litigation (JPML) consolidated the cases in this Court by Order dated December 18, 2001 pursuant to 28 U.S.C. § 1407. Shortly after this MDL was established, this Court appointed a Plaintiffs Steering Committee to act on behalf of all Plaintiffs while the MDL was ongoing.

Class Action Complaint

In May 2002, the Plaintiffs' Steering Committee filed a Master Class Action Complaint. A First Amended Class Action Complaint was filed shortly thereafter

[1]Rhabdo is an acute, fulminating, potentially fatal disease of the skeletal muscle, which entails destruction of skeletal muscle. Stedman's Medical Dictionary, 24th Ed., Williams & Wilmkins, 1982.

(hereinafter the "Class Action Complaint" or "CAC"). In the CAC, Plaintiffs allege that when the FDA initially approved Baycol, Defendants knew it was less effective than the other statins on the market. CAC ¶ 29. Because Defendants were not claiming that Baycol was superior to other statins already on the market, Baycol was approved after clinical trials only involving 3,000 people; a number far less than the numbers used for other statins. Id. ¶ 30. The statin market is enormous, and Defendants allegedly viewed Baycol as a blockbuster product. Id. ¶ 31. Through aggressive marketing, and a price well below the other statins, Defendants were able to obtain a 5% market share before Baycol was withdrawn from the market. Id. ¶ 33.

The first reported death linked to Baycol ingestion occurred in 1998, the first year Baycol was on the market. Id. ¶ 36. Thereafter, more than 100 additional deaths worldwide have been linked to Baycol use. Id. ¶ 37. In addition, clinical studies and adverse events reports revealed injury in another 1,000 cases, although Plaintiffs believe this number to be much higher. Id. Although Defendants were aware of these results, Defendants are alleged to have failed to disclose this information to the FDA, the medical community and the public. Id. ¶¶ 39-41. Also, the "Warning" issued by Defendants in 1998 was inadequate because it did not put the medical community on notice of Baycol's dangerous propensities. Id. ¶¶ 42-47. When the FDA ordered Defendants to make certain changes in the Baycol labeling one month later, the resulting "Warning" remained inadequate to warn of Baycol's risks. Id. ¶¶ 44-45.

Defendants also allegedly launched an advertising campaign trumpeting Baycol's "proven performance", "exceptional value" and "powerful strength", without disclosing

the risks associated with Baycol. Id. ¶¶ 48-49. The FDA later ordered Defendants to change the promotional material based on its finding that it was "false, lacking in fair balance, and otherwise misleading." Id. ¶ 50.

To obtain approval for higher doses of Baycol, Defendants were required to undertake three "formulary switch conversion studies." It is alleged that the results of these studies demonstrated Baycol's dangers, especially in the cases of increased dosages. Id. ¶ 57. But despite these results, Defendants pushed ahead to obtain approval for the higher doses. Id. ¶¶ 56 - 68.

After the 0.8 mg dosage was approved by the FDA, Defendants began advertising the virtues of this dosage without disclosing the risks associated with higher dosages. Id. 63. The number of adverse events reported was so alarming that by the fall of 2000, Baycol was put on a watch list by the German Health Industry. Id. 66. Because the number of adverse reports continued to increase, the Arznei Telegram, a drug safety information bulletin based in German, published a warning concerning the use of Baycol in March 2001. Id. 67.

In April 2001, the FDA again mandated stronger warnings in the Baycol labeling. Id. ¶ 69. Then in May 2001, Defendants were compelled to issue a "Dear Healthcare Professional" letter. In this letter, Defendants called attention to some of the dangers associated with Baycol use, particularly when combined with gemfibrozil. Id. ¶ 71.

In July 2001, France's drug control agency issued a warning of the problems associated with Baycol use. Id. 72. That same month, the European Medicines

Evaluation Agency announced it was investigating the side effects of Baycol. Id. Then, on August 8, 2001, Defendants withdrew Baycol from the market. Id. ¶ 77.

Based on the above allegations, Plaintiffs allege that Defendants falsely and deceptively misrepresented or omitted material information as to Baycol's risks to the FDA, the medical community and the public, as demonstrated by inadequate warning labels, and misleading advertising. Despite knowledge of Baycol's risks, Defendants allegedly continued to promote Baycol in a vigorous manner, and push for approval of higher doses. Plaintiffs allege that through Defendants' conduct, they were proximately injured and have suffered losses. Based on such conduct, Plaintiffs have asserted claims of strict products liability (failure to warn), strict products liability (design defect); negligent failure to warn; negligence per se; breach of implied warranty; unjust enrichment; medical monitoring, and breach of warranty against redhibitory defects (under Louisiana law). Plaintiffs also allege that due to Defendants' oppression, fraudulent concealment, wantonness, malice, and reckless disregard for the safety of Plaintiffs, Plaintiffs are entitled to punitive or exemplary damages.

In the Class Action Complaint, Plaintiffs seek certification of the following classes:

1. A personal injury class consisting of all persons who claim physical injury caused by Baycol;

2. A medical monitoring class consisting of persons who took Baycol and are currently asymptomatic; and

3. A refund class consisting of all persons who purchased Baycol for personal or family use.

Plaintiffs have also presented the Court a proposed Trial Plan. Plaintiffs propose two phases for a Class Trial. In Phase I, the Court would conduct the Class Trial, in which the claims of the named representatives would be tried under the Minnesota choice of law rules. The jury would also hear evidence of compensatory and punitive damages as to the named representatives. The jury would also hear evidence as to common factual issues. Specifically, Plaintiffs propose that the following issues be tried:

Was Baycol unreasonably dangerous?

Did Defendants negligently develop, test or market Baycol?

Did Defendants conceal, omit, suppress or misrepresent material information about the risks and safety of Baycol?

Did Defendants fail adequately to warn consumers about the dangers of Baycol including, but not limited to, its side effects?

Did Defendants recklessly expose class members to a product not reasonably fit for its intended use?

Did Defendants breach warranties in the marketing and sale of Baycol?

Did Defendants' actions and omissions warrant the imposition of punitive damages?

If so, what is the just ratio or aggregate amount?

Should Defendants be required to pay back to class members the money paid for Baycol, because class members did not receive a safe or efficacious drug?

Plaintiffs also propose that during the course of the trial, the Court would consider evidence relative to the equitable remedies of medical monitoring and restitution/disgorgement for unjust enrichment. Phase II would involve individual class member suits in the transferor districts, if Plaintiffs prevail in Phase I.

Standard for Class Certification

The class action serves to conserve the resources of the court and the parties by permitting an issue that may affect every class member to be litigated in an economical fashion. Jenkins v. Raymark Industries, Inc., 782 F.2d 468, 471 (5th Cir. 1986)(quoting General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 155 (1979)). Whether an action should be certified as a class action is governed by Rule 23 of the Federal Rules of Civil Procedure.

Pursuant to Rule 23(a), there are four threshold requirements to class certification:

> 1) the class is so numerous that joinder of all members is impracticable; 2) there are questions of law or fact common to the class; 3) the claims or defense of the representative parties are typical of the claims or defenses of the class; and 4) the representative parties will fairly and adequately protect the interests of the class.

A district court should not certify a class until it has been determined, "through rigorous analysis, that all the prerequisites of Rule 23(a) have been satisfied. General Telephone Co. of Southwest v. Falcon, 457 U.S. at 161. If these prerequisites are met, the Court must then determine if the putative class is maintainable under Rule 23 (b)(1), (2) or (3). Plaintiffs bear the burden of proof regarding the Rule 23 requirements. In re Worker's Compensation, 130 F.R.D. 99 (D. Minn. 1990). Nonetheless, district courts ultimately retain broad discretion in determining whether or not to certify a class. Gilbert v. City of Little Rock, Ark., 722 F.2d 1390, 1399 (8th Cir. 1983).

In this case, Plaintiffs' burden is great. Many courts presiding over similar products liability cases involving prescription drugs have denied similar requests for class

certification. See, In re Paxil Litigation, 212 F.R.D. 539 (C.D. Cal. 2003); In re Rezulin Products Liability Litigation, 210 F.R.D. 61 (S.D.N.Y. 2002); In re Phenylpropanolamine ("PPA") Products Liability Litigation, 208 F.R.D. 625 (W.D. Wash. 2002); In re Propulsid Products Liability Litigation, 208 F.R.D. 133 (E.D. La. 2002); Valentino v. Carter-Wallace, Inc., 97 F.3d 1227 (9th Cir. 1996). These courts have all recognized that a products liability action is distinguishable from the "typical" mass tort. With regard to the "typical" mass tort case, proximate cause can be determined on a class-wide basis, whereas in a products liability case, individual issues must be considered in determining proximate cause and the alleged tortfeasor's affirmative defenses may depend on facts peculiar to each plaintiff. In re Dalkon Shield IUD Products Liability Litigation, 693 F.2d 847, 853 (9th Cir. 1982).

To date, no Court of Appeals decision has approved class certification of an action involving prescription drugs. Plaintiffs nonetheless argue that when Rule 23 of the Federal Rules of Civil Procedure was drafted, complex litigation, such as mass tort or products liability cases as we now know them, did not exist, nor were such cases envisioned. Hearing Transcript ("HT) p. 37. For this reason, Plaintiffs assert, it is not surprising that a mass products liability case, such as the case currently before the Court, does not easily fall within the parameters of Rule 23. With this in mind, Plaintiffs ask the Court to embrace the purposes of the Rules of Civil Procedure as set forth in Rule 1; to construe and administer the Rules "to secure the just, speedy and inexpensive determination of every action." It is Plaintiffs' position that class certification is the procedural device that will best serve this purpose in this case. Plaintiffs further argue

that other courts, through a liberal application of the Rules, have granted class certification in products liability litigation. See eg., In re Copley Pharmaceutical, Inc. "Albuterol" Products Liability Litigation, 158 F.R.D. 485 (D. Wyo. 1995); Jenkins v. Raymark Indust., Inc., 782 F.2d 468 (5th Cir. 1986); In re Agent Orange Product Liability Litigation, 506 F. Supp. 762 (E.D.N.Y. 1980); In re: West Virginia Rezulin Litigation, 585 S.E. 2d (W.Va. 2003). See also, Cafky et al. v. Bayer Corporation et. al., Case No. 98,111 (Okla. Ct. App. 2003); Bouchchanskaia v. Bayer Inc., 2003 BCSC 1306.[2]

The Court is well aware of its judicial obligation to administer "just, speedy and inexpensive" justice and that in the appropriate circumstance, class certification best serves this obligation. As directed by Rule 23 and applicable case law, however, class certification is not proper unless *all* of Rule 23's prerequisites are met. Taking into consideration the unique nature of the Baycol litigation, which involves a prescription drug that, like most prescription drugs carries certain risks, even the most liberal application of Rule 23 warrants a finding that class certification is not appropriate on the record currently before the Court.[3]

I. Personal Injury Class

Plaintiffs seek to certify a personal injury class under Rule 23(b)(3) and (c)(4). The named representatives for this class are: 1) Katherine Swearengin - a Colorado

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[2]While the Cafky and Bouchanskaia cases involve similar personal injury claims arising from the use of Baycol in which the courts granted similar requests for class certification, this Court respectfully disagrees with the conclusions reached in those decisions for the reasons set forth in this Memorandum.

[3]In reaching this determination, the Court has taken into consideration all submissions to the Court up to the date of this Order. To this end, the Court will deny Defendant's motion to strike, filed on June 27, 2003.

resident who took .8 mg per day for two weeks in October 2000. She suffered rhabdo and was hospitalized. She continues to suffer residual injuries, harm and loss; 2) Joseph D' Agui - a New Jersey resident who took .4 mg per day from October 2000 to August 2001. He suffered from rhabdo and continues to suffer residual injuries, harm and loss; and 3) Edward Sample - an Arkansas resident who took .3 mg of Baycol, together with 600 mg per day of gemfibrozil, from October 1999 until he was hospitalized in January 2000 with rhabdo. He continues to suffer residual injury, harm and loss. This class would seek recovery under the following theories: strict products liability, failure to warn and negligence *per se*.

A. 23(a) Prerequisites

1. Numerosity

A class should be certified only if the "class is so numerous that joinder of all members is impracticable". Rule 23(a)(1). Plaintiffs allege that approximately 900,000 persons in the United States purchased or took Baycol. Of these, Plaintiffs estimate that thousands of persons would fall into the personal injury class. Clearly, this prerequisite is met.

2. Commonality

The next prerequisite focuses on questions of law and fact common to the class. Rule 23(a)(2). It is not necessary that all questions of law and fact are common to the class, rather the commonality requirement is met were, for example, "the question of law linking the class members is substantially related to the resolution of the litigation, even though the individuals are not identically situated." Paxton v. Union Nat'l Bank, 688

F.2d 552, 561 (8th Cir. 1982)(quoting American Finance Sys., Inc. V. Harlow, 65 F.R.D. 94, 107 (D. Md. 1974)). In this case, Plaintiffs assert that there are questions of law and fact common to all cases, such as whether Baycol causes injury, whether Defendants concealed adverse events from the FDA, and whether Defendants failed to adequately warn of the risks of Baycol. Defendants do not dispute that there are common questions of law and fact, but that individual issues of fact and law predominate making class certification improper. Under Rule 23(a)(2), however, the Court is not concerned with predominance. Accordingly, the commonality prerequisite is met.

3. Typicality

Rule 23(a)(3) requires that the claims or defenses of the representative parties are typical of the claims or defenses of the class. This requirement focuses on the similarity of the legal and remedial theories behind the claims. Jenkins, 782 F.2d at 472. "It is intended to assure the claims of the class representatives are similar enough to those of the class, so that the representatives will adequately represent the class." Day v. NLO, Inc., 144 F.R.D. 330, 334 (S.D. Ohio 1992). In other words, in determining typicality, the court must consider whether the representative's interests will be aligned with those of the represented group, and in pursuing his own claims, the named plaintiff will also advance the interests of the class members. In re: American Medical Systems, Inc., 75 F.3d 1069, 1082 (6th Cir. 1996). Although factual differences may exist amongst the claims, such differences will not preclude class certification when the claims arise from the same course of conduct and gives rise to the same legal or remedial theories. Alpern v. UtiliCorp United, Inc., 84 F.3d 1525, 1540 (8th Cir. 1996).

Plaintiffs argue the claims of the class representatives are typical of the class, because they arise from a single product and the same conduct. Further, Plaintiffs argue that the class representatives assert identical legal claims; personal injury resulting from the ingestion of Baycol under the theories of failure to warn, negligence and design defect.

While these claims involve common issues, they also involve individual issues such as injury, causation, the learned intermediary doctrine and comparative fault. Because of the individual issues involved, Defendants argue that the named Plaintiffs for the personal injury class do not, and cannot, advance the interests of all class members given the myriad permutations involved. Thus, their claims are not typical of the class and they will not adequately represent the class.

For example, one of the named representatives, Ms. Swearingen, was prescribed .8 mg of Baycol in October 2000. A finding that Defendants were negligent in marketing .8 mg in October 2000 does not necessarily support a finding that Defendants were negligent in marketing .2 mg in 1999 because the state of Defendants' knowledge may be different in 2000 as compared to 1999. Similarly, class representative Edward Sample took .3 mg Baycol with 600 mg gemfibrozil from October 1999 to January 2000. A finding in support of his claim that Defendants negligently failed to warn of the dangers of concomitant use of Baycol and gemfibrozil does not necessarily support a finding of negligence with regard to monotherapy.

The Court agrees that the underlying facts and circumstances of this case do not make the proposed personal injury class amenable to class certification. This case

involves a vast number of persons who took different dosages of Baycol, at different times, and possibly took Baycol concomitantly with other prescription drugs. Because the theories asserted by this putative class are based on what Defendants' knew at the time Baycol was prescribed, and whether Defendants acted reasonably based on such knowledge, the claims of the named representatives are not typical of the class. In addition, the named plaintiffs' claims are not typical of the class because their claims are subject to unique defenses. Again, focusing on the claims of Ms. Swearingen, she was started on a dosage of .8 mg. In defense of Ms. Swearingen's claim, Defendants claim they will argue that they are not liable for her injuries because the Baycol label at that time indicated that .4 mg was the starting dosage, and the letter sent to health care providers when the .8 mg was launched indicated that patients should only be titrated to the .8 mg dose. This defense, however, is only applicable to those class members who were started at .8 mg, and thereafter suffered an injury.

Other courts have recognized that limitations exist when the claimed injury is tied to a complex course of conduct engaged in by the defendants over a long period of time, as opposed to a single act to which all class members were exposed to equally. See, eg., Clay v. American Tobacco Company, 188 F.R.D. 483, 492 (S.D. Ill. 1994)(citing cases); In re Paxil Litigation, 212 F.R.D. at 550 (the typicality requirement will not be met where factual differences exist among plaintiffs, even in a case with a single defendant and a single product because differences may force the named representatives to make arguments at trial that may be adverse to another class member's claim).

In a recent decision issued in this District, the court certified a personal injury class in an action involving an allegedly defective heart valve. St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation, 2003 WL 1589527 (D. Minn. 2003). The court acknowledged that generally, medical products liability cases involved proof of individualized issues. Id. at *5. The court found, however, that the case before it was distinguishable from typical medical products liability actions because it involves only one product, one defect and causation was not the overarching issue. Although the Baycol case involves one product and one manufacturer, the alleged defect may be related to dosage, of which four were available at different times while Baycol was on the market, and may be related to concomitant use. Furthermore, causation is the overarching issue, as Defendants do not dispute that Baycol can cause injury, rather they argue that injury can only be determined on an individualized basis.

The Court thus finds that the factual differences among the class members claims and the defenses to which such claims are subject, the claims of the named representatives are not typical of the class.

4. Adequacy

The final prerequisite requires the Court to make a determination that the named class representatives and counsel[4] will adequately represent the class members. In making this determination, the Court must ascertain whether the named representatives' interests are sufficiently similar to those of the class to the extent that is unlikely that their goals and viewpoints will diverge. In re: St. Jude Medical, 2003 WL 1589527 *3

[4]There is no challenge to the adequacy of class counsel.

(quoting Parkhill v. Minnesota Mutual Life Ins. Co., 188 F.R.D. 332, 339 (D. Minn. 1999)). For the reasons stated above, specifically the factual differences and differing defenses, Plaintiffs have failed to demonstrate that the goals and viewpoints of the named representatives will not diverge.

B. 23(b)(3) Requisites

A class may be certified under Rule 23(b)(3) when "questions of law or fact common to the members of the class predominate over any questions affecting only individual members and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Rule 23(c)(4) provides that "[w]hen appropriate (A) an action may be brought or maintained as a class action with respect to particular issues, or (B) a class may be divided into subclasses and each subclass treated as a class . . ." Defendants oppose class certification of a personal injury class as proposed by Plaintiffs because individual issues of fact and law predominate. Plaintiffs recognize that causation and damages are individual issues that cannot be tried on a class basis. Plaintiffs propose that the common issues of product defect and Defendants' compensatory and punitive liability issues, including generic causation, be certified pursuant to Rule 23(c)(4). Prior to making predominance and superiority determinations, however, the Court must determine which state laws will apply to the asserted claims. Castano v. American Tobacco Co., 84 F.3d 734, 740 (5th Cir. 1996).

1. Choice of Law

In determining which substantive law applies, federal courts apply the choice of law rules of the forum state. Minnesota has adopted a five factor choice influencing

analysis in Milkovich v. Saari, 203 N.W.2d 408 (Minn. 1973). Nesladek v. Ford Motor Company, 46 F.3d 734, 738 (8th Cir. 1995). These factors are: 1) predictability of results; 2) maintenance of interstate order; 3) simplification of judicial task; 4) advancement of the forum's governmental interests; and 5) the better rule of law. Id. at 738-741.

The first and third factors, predictability of results and simplification of judicial task, have generally not been applied in tort cases. See, Hughes v. Wal-Mart Stores, Inc., 250 F.3d 618, 620 (8th Cir. 2001); Nodak Mutual Insurance Co. v. American Family Mutual Insurance Co., 604 N.W.2d 91, 94-95 (Minn. 2000). Further, the Minnesota courts have not placed any emphasis on the fifth factor for nearly twenty years. Nodak, at 96. Thus, the choice of law issue in this case will be determined by consideration of only maintenance of interstate order and advancement of the forum's governmental interests.

> Maintenance of interstate order is concerned with
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> whether the application of Minnesota law would manifest disrespect for [other state] sovereignty or impede the interstate movement of people and goods. An aspect of this concern is to maintain a coherent legal system in which the courts of different states strive to sustain, rather than subvert, each other's interests in areas where their own interest are less strong.

Nodak, at 95. In Hughes, the Eighth Circuit held that this factor weighs in favor of the state which has the most significant contacts with the facts relevant to the litigation. Id. at 621. In that case, the court held that the state in which the accident occurred, and in which the plaintiff lived, had the more significant contact compared to the state in which the defendant corporation had its headquarters. Id. Applying this analysis to the facts of

this case, it is clear that this factor supports application of the state law in which the plaintiff resides, as Baycol was prescribed and ingested in the state of the plaintiff's residence, and the alleged injury occurred in the state of the plaintiff's residence.

The advancement of the forum's governmental interest factor generally weighs in favor of application of the state law in which the plaintiff lives and in which the injury occurred. See eg., Hughes, supra; Nodak, supra. In the present case, as the injury occurred in the state of plaintiff's residence, the substantive law of the state of plaintiff's residence should be applied to their claims.

Plaintiffs argue, however, that as Bayer Corporation and GlaxoSmithKline are headquartered in Pennsylvania, and that Bayer Pharmaceutical is located in Connecticut, the law of either Pennsylvania or Connecticut can be constitutionally applied to the claims of the Class Action Complaint. The Eighth Circuit, however, has not given the docile of the corporate defendant much weight in tort cases. See, Hughes, 250 F.3d at 621. See also, In re: Bridgestone/Firestone, Inc., 288 F.3d 1012, 1016-1017 (7th Cir. 2002)(rejecting application of uniform place-of-the-defendant's-headquarters rule to product liability cases).

As the above analysis indicates, in the event of a conflict, the law of the state in which the plaintiff resides will govern the claim.

2. Predominance

a. Individual Issues of Law

Plaintiffs acknowledge that there may be differences in the state laws that apply to the various products liability claims, but that for the most part, the state laws are

consistent, or if different, the differences can be handled through sub-classes. Plaintiffs assert that courts in other jurisdictions have certified common issues of liability in a nationwide class applying all states' laws where individual damages cases were still necessary. See eg., In re: Copley Pharmaceutical, Inc., 161 F.R.D. 456 (D. Wyoming 1995).

Defendants argue that the applicable state laws controlling the claims of the personal injury class differ from jurisdiction to jurisdiction and that the issues are too complex for class treatment. Defendants point out that application of comment k of § 402A of the Restatement of Torts (Second) to prescription drugs and devices varies from state to state. For example, Pennsylvania has held that strict liability claims do not apply to prescription drugs, Hahn v. Richter, 673 A.2d 888, 890-891 (Pa. 1996), while California courts have uniformly applied comment k to prescription drugs, Brown v. Superior Court, 751 P.2d 470, 477 (Cal. 1988), and Florida, Illinois and Nebraska treat comment k as an affirmative defense. Adams v. G.D. Searle & Co., Inc., 576 So.2d 728, 731-33 (Fla. Dist. Ct. App. 1991); Glassman v. Wyeth Labs, Inc., 606 N.E.2d, 338, 342-344 (Ill. App. Ct. 1992); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 840 (Neb. 2000).

Differences in state law, no matter how slight, are important and must be determined prior to certification because such differences "may swamp any common issues and defeat predominance." Castano, 84 F.3d at 741. See also, In re the Matter of Rhone-Poulenc Rorer Inc., 51 F.3d 1293, 1300 (7th Cir. 1995)(demonstrating significance in the difference in state law by comparing differing state pattern

instructions on negligence and differing judicial formulations of the meaning of negligence and the subordinate concepts). The Court has not received from Plaintiffs a thorough analysis of the differences in state law, nor suggestions as to how the state laws can be divided into subclasses. For Plaintiffs to suggest that the Court can review the state laws and create the appropriate subclasses at some later date is not sufficient to meet their burden to demonstrate that class certification is appropriate. See In re Paxil, 210 F.R.D. at (p. 10 of slip op)(court not content to certify an action and then handle the problems raised by the parties at a later stage). See also, Castano, 84 F.3d at 741 ("Given the plaintiffs' burden, a court cannot rely on assurances of counsel that any problems with predominance or superiority can be overcome.") Plaintiffs have thus failed to meet their burden of demonstrating that common issues of law predominate.

b. Individual Issues of Fact

Plaintiffs further argue that common questions of fact predominate, because to obtain relief, Plaintiffs "must establish that Defendants knew, but did not adequately disclose, the incidence of adverse side effects caused by Baycol and that Baycol was defective and unreasonably dangerous. The who, what, where and why needed to establish Plaintiffs' claims does not differ from class member to class member." Memorandum of Law in Support of Plaintiffs' Motion for Class Certification, p. 50. This statement, however, is not correct. As noted previously, Plaintiffs' claims of failure to warn turn on what Defendants knew at the time Baycol was prescribed. As the class members were prescribed Baycol at different times, the issue of Defendants' knowledge will differ from case to case. The same is true for the claims based on negligence. For

example, negligence claims depend on individual facts - whether there is a breach of duty or the foreseeability of harm will depend on what Defendants knew or should have known at the time Baycol was prescribed and whether Defendants acted reasonably based on the knowledge it had at that time. With respect to the claims of design defect, liability cannot be established without consideration of individualized issues such as dosage. Plaintiffs' expert, Dr. Kaysen has opined that the risk of rhabdo is dose-related. Kaysen Dep., Ex. 4 at 53. He also testified that age, previous renal insufficiency and various drug interactions influence the risk of rhabdo. Id. At 58-60. Because these individualized issues are inextricably intertwined with the common issues identified by Plaintiffs, the common issues do not predominate rendering certification under subdivision (b)(3) inappropriate.

This conclusion does not change with respect to certification under subdivision (c)(4). The Court notes that there is disagreement as to the proper scope of certification under subdivision (c)(4). In Castano, the Fifth Circuit rejected the plaintiffs' attempt to avoid the predominance requirement by seeking certification pursuant to Rule 23(c)(4).

> Severing defendants' conduct from reliance under rule 23(c)(4) does not save the class action. A district court cannot manufacture predominance through the nimble use of subdivision (c)(4). The proper interpretation of the interaction between subdivisions (b)(3) and (c)(4) is that a cause of action, as a whole, must satisfy the predominance requirement of (b)(3) and that (c)(4) is a housekeeping rule that allows courts to sever the common issues for trial . . . Reading rule 23(c)(4) as allowing a court to sever issues until the remaining common issue predominates over the remaining individual issues would eviscerate the predominance requirement of rule 23(b)(3); the result would be automatic certification in every case where there is a common issue, a result that could not have been intended.

Castano, at 745, n. 21. Other courts have adopted this rationale. See, In re Dow Corning Corporation, 211 B.R. 545 (Bkry E.D. Mich. 1997); In re Jackson National Life Insurance Co. Premium Litigation, 183 F.R.D. 217, 224-225 (W.D. Mich. 1998). See also, Benner v. Becton Dickinson & Co., 214 F.R.D. 157 (S.D.N.Y. 2003)(finding class certification pursuant to subdivision (c)(4) not appropriate where such certification did not make case more manageable, and individual issues still predominated.)

Yet other courts have held that certification under subdivision (c)(4) does not require a finding that common issues predominate.

> The provision is intended to advance judicial economy by permitting adjudication of any issues common to the class even though the entire litigation may not satisfy the requirements of Rule 23. *See* 7B Wright and Miller, *supra,* § 790, at 271. In other words, "when common questions do not predominate when compared to all questions that must be adjudicated to dispose of a suit, Rule 23(c)(4) asks whether a suit limited to the unitary adjudication of a particular common issues will achieve important and desirable advantages of judicial economy and efficiency." 1 *Newburg, supra,* § 4.25, at 4-81. Certification is improper if "noncommon issues are inextricably entangled with the common issues, or ... the noncommon issues are too unwieldy or predominant to be handled adequately on a class action basis." Wright and Miller, *supra* § 1790, at 276.

Emig v. American Tobacco Co. Inc., 184 F.R.D. 379, 395 (D. Kan. 1998) Accord, Valentino v. Carter-Wallace, Inc., 97 F.3d at 1234 (finding that rule 23 authorizes the district court to isolate common issues under subdivision (c)(4), even if common issues do not predominate over individual questions, yet decertified class because district court did not adequately consider predominance requirement.); In re Tetracycline Cases, 107 F.R.D. 719 (W.D. Mo. 1985).

The Eighth Circuit has not provided any guidance on this issue, but this Court finds the interpretation adopted in Emig, Valentino and Tetracycline to be more

persuasive. Under such interpretation, however, certification in this case under subdivision (c)(4) is not appropriate because the individual issues are inextricably intertwined with the common issues. Furthermore, certification under (c)(4) will not make the case more manageable, as application of the laws of 51 jurisdictions will infuse complexity into a class trial, and individual trials will still be required to determine issues of causation, damages, and applicable defenses. As a result, a class trial will not materially advance this litigation.

3. Superiority

Finally, prior to certification, the Court must decide whether a class action is superior to other methods of adjudication. This factor requires the Court to determine whether the class action is manageable, taking into consideration choice of law determinations, Erie guesses, and notice to class members. Castano, 84 F.3d at 747. As discussed above, however, Plaintiffs have failed to demonstrate that, given the application of the various state laws, such a class action would be manageable. Where plaintiffs have failed to provide the court clearly defined classes, based on the variations in state law, the superiority requirement has not been met. In re Telectronics Pacing Systems, Inc., 168 F.R.D. 203, 219 (S.D. Ohio 1996). See also, In re Paxil Litigation, 210 F.R.D. at 551 (risk of jury confusion, when taken together with risk of improperly grouping different states' laws, outweighs any possible advantages to be gained from certification).

The most compelling rationale for finding superiority in a class action is whether the action is a negative value suit. Castano, at 748. The personal injury claims,

however, do not present such a suit. As a matter of record, Bayer has settled close to 1000 personal injury cases to date, and the amount of these settlements clearly establish that the value of the personal injury suit is substantial.

II. Medical Monitoring Class

Plaintiffs also seek to certify a class pursuant to subdivision (b)(2), or in the alternative (b)(3), as to the claims for medical monitoring. Through their claim for medical monitoring, Plaintiffs seek a medical monitoring program that will:

a. Notify Baycol users of the potential harm from Baycol;

b. Fund further studies of the long term effects of Baycol on users;

c. Fund research into possible cures for the detrimental effects of using Baycol;

d. Gather and forward to treating physicians information related to the diagnosis and treatment of injuries which may result from using Baycol; and

e. Aid in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of Baycol users.

CAC ¶ 124.

With respect to the early diagnosis aspect of the program, Plaintiffs specifically seek a program by which class members may receive a periodic blood test to measure serum creatinine and blood pressure testing. Plaintiffs allege that such testing is necessary because the injuries that can be caused by Baycol, most prominently rhabdo, may not be diagnosed, which if left untreated, will lead to serious future injury including kidney failure and End-Stage Renal Disease ("ESRD"). Kaysen Aff. ¶¶ 18-25; Declaration

of Donald C. Arbitblit. The requested testing is alleged to be a reliable means to detect such injury.

The class is defined as those persons who took Baycol that are currently asymptomatic. The named plaintiffs for this class are: 1) Jack Hartman - a Minnesota resident who took .3 mg per day from November 1999 through August 2001 – alleged to have suffered muscle aches and pains; 2) William Krohn - a Minnesota resident who took .3 mg per day in 1999; 3) Tina Coutain - an Illinois resident who took .3 mg per day from July 1999 through August 2001 – alleged to have suffered muscle aches and pains; 4) Pearl Dardar - a Louisiana resident who took Baycol daily starting in 2000 and suffered muscle aches and pains; 5) Marsha Miller, who is also a member of the Refund Class, is a resident of Ohio who took .3 mg per day in March 1999. In May 2000, her dosage was increased to .4 mg per day until the spring of 2001 – alleged to have suffered aches and pains, together with generalized fatigue.

A. Rule 23(a) Requirements

Defendants do not dispute that the numerosity and commonality requirements are met with regard to the medical monitoring class.

Defendants do, however, argue that the typicality and adequacy requirements are not met because the named plaintiffs have alleged that they each suffered from a physical injury attributable to Baycol, and that they have all received the testing that Plaintiffs propose. Plaintiffs respond that the named plaintiffs are typical of the putative class because all are seeking medical monitoring as a result of ingesting Baycol - because all are at risk of kidney disease. Their interests are also coextensive with that of the

class, they argue, because they seek a Defendant-funded medical monitoring program. The fact that the named plaintiffs have suffered an injury does not preclude them from representing the interests of the class because they are currently asymptomatic, and there is no evidence that they would not vigorously litigate this claim.

Given the nature of a medical monitoring claim, the Court is not convinced that the named representatives will adequately represent the interests of those class members who have not suffered any injury as a result of taking Baycol, and who have not received the requested testing.

Some states treat medical monitoring as an independent cause of action, see eg., Redland Soccer Club v. Dept. of the Army, 548 Pa. 178, 696 A.2d 137 (Pa. 1997), while others recognize medical monitoring as a form of damages to an underlying tort, such as negligence or strict liability. See eg., Potter v. Firestone Tire & Rubber Co., 6 Cal. 4th 965 (1993). Other states have not yet addressed medical monitoring in any way. See, Lockridge Declaration, Ex. F. Of the states that have recognize medical monitoring, some require a showing of injury as a prerequisite to recovery, while other states do not require such a showing. See, Hinton v. Monsanto Co., 813 So.2d 827 (Ala. 2001)(no cause of action for medical monitoring absent physical injury); but see, Redland Soccer, supra (recognize medical monitoring in absence of physical injury). Also, of those states that have recognized an independent cause of action for medical monitoring, the plaintiff must show that the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Redland Soccer, 696 A.2d at 145-146. As the named representatives allege injury, and have already received the tests advocated by

Plaintiffs' expert Dr. Kaysen, the named representatives will not adequately represent the interests of those who have suffered no injury, and who have not received the requested testing.

B. 23(b)(2)

Even if Plaintiffs could show that the Rule 23(a) prerequisites are met, they have failed to show that class certification pursuant to subdivision (b)(2) is appropriate. Rule 23(b)(2) provides for class certification of an action seeking declaratory or injunctive relief where "the party opposing the class has acted or refused to act on grounds generally applicable to the class". Although there is no predominance or superiority requirement under this subdivision, the Court must nonetheless determine whether individual issues exist among the class members, which would destroy the cohesive nature of the class claims. In re Diet Drugs, 1999 U.S. Dist. LEXIS 13228, at *24 (E.D. Penn. 1999)(citing Barnes v. The American Tobacco Company, 161 F.3d 127, 143 (3rd Cir. 1998)); Thompson v. American Tobacco Company, 189 F.R.D. 544 (D. Minn. 1999); In re Rezulin, 210 F.R.D. at 75. A class will not be cohesive if factual differences amongst the class members "translate into significant legal differences." Barnes, at 143.

Of the states that do recognize medical monitoring as an independent cause of action, the elements of such a claim appear to be the same. In Florida, for example, plaintiffs must prove exposure to a proven hazardous substance, caused by defendant's negligence, as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease, a monitoring procedure exists to make early detection possible, the prescribed monitoring regime is different from that normally

recommended in the absence of exposure and the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles. Petitio v. A.H. Robins Co., Inc., 750 So.2d 103 (Fla. Dist. Ct. App. 1990). See also, Redland Soccer, supra (same); Bower v. Westinghouse Elec. Corp., 522 S.E.2d 424 (W. Va. 1999)(same); Hansen v. Mountain Fuel Supply Co., 858 P.2d 970 (Utah 1993)(same). In California, where medical monitoring is considered an element of damages, a plaintiff may be entitled to medical monitoring damages only if the plaintiff can show, through reliable medical expert testimony, that the need for future medical monitoring is a reasonably foreseeable consequence of exposure to toxic chemicals and that the recommended monitoring is reasonable. Potter, 6 Cal. 4th at 1006. In the District of Columbia, the determination of the type and extent of medical monitoring will be based on the "*individual's* specific health situation." Reed v. Philip Morris, Inc., 1997 WL 538921, * 17 (D.C. Super. 1997).

Although the states have not addressed medical monitoring in a uniform way, it appears that whether such a claim is recognized as an independent cause of action, or an element of damages, the state laws generally require a finding that a plaintiff's exposure to a toxic substance was due to defendant's negligence. See eg., Redland Soccer, 696 A.2d at 145-146; Potter, 6 Cal. 4th at 1006. As discussed previously, however, a finding of negligence is inextricably intertwined with individual issues. As a result, individual issues will undermine the cohesion of the medical monitoring class.

Defendants also argue that given the differences in state law governing medical monitoring claims, a unitary trial of the proposed common ground would be

unworkable. Plaintiffs argue that the differences in state law should not preclude class certification, as such differences can be addressed through sub-classes. In support, Plaintiffs cite to In re Diet Drugs, 1999 U.S. Dist. LEXIS 13228 (E.D. Pa. 1999), in which the district court conditionally certified a medical monitoring class despite the variances in state law and the acknowledgment that the determination of individual issues may ultimately render certification unacceptable. Plaintiffs have not, however, sufficiently addressed how the Court would manage the class through subclasses, nor have they sufficiently established what the subclasses would be and which states would be grouped in which subclass. Plaintiffs cannot meet their burden of demonstrating that class certification is superior.

The Court would further note that this case is distinguishable from the Diet Drugs case, because in Diet Drugs, the record included "sufficient medical study and research" to support a conditional certification. Id. *51. In a case very similar to this case, the district court denied a similar request for class certification of a medical monitoring class. In re Propulsid Litigation 208 F.R.D. at 147. In that decision, the court denied certification of a medical monitoring class, based on plaintiffs' failure to brief the variations in state law which apply to this claim, and because "[n]either the FDA, nor any medical organization or institution, nor any else for that matter, except the plaintiff's expert, has recommended or suggested that a program of medical monitoring or a group study of all former Propulsid users be undertaken." 208 F.R.D. at 147. "[T]he question is whether the courts should lead the scientific community in an area of medical science." Id. The court went on to distinguish the Diet Drugs case in which a medical

monitoring class was conditionally certified, based, in part, on the fact that the United States Department of Health and Human Services had recommended the form of medical monitoring sought in the litigation. Id.

As in Propulsid, there is a lack of medical or scientific evidence, with the exception of Plaintiffs' expert, which suggests or recommends that individuals who took Baycol, and have remained asymptomatic, should have their creatinine levels and blood pressure tested.

In further support of its motion, Plaintiffs again rely on the recent decision issued in In re St. Jude Medical, Inc., 2003 WL 1589527 (D. Minn. 2003) in which the court conditionally granted class certification under subdivision (b)(2) with respect to the medical monitoring class in litigation involving a heart valve. In determining the appropriateness of certification of the medical monitoring class, the court distinguished the case before it from the Rezulin decision, noting that Rezulin involved complicated facts, "as class member took [the drug] at different times, for different periods, in different amounts, and while undergoing different levels of . . . health monitoring." Id. By contrast, the court found that the case before it "involves a discrete and ascertainable number of valve recipients", and that "[I]t is known exactly how long each person had the Silzone valve and the circumstances of the implant. These facts are more readily ascertainable than the drug-related information in Diet Drugs , and certainly more so than Rezulin." Id. * 15-16.

Contrary to Plaintiffs' argument, this case is analogous to the Rezulin case, rather than In re St. Jude Medical, as class members took Baycol at different times, in different amounts, with different co-prescriptions and with different medical backgrounds.

C. 23(b)(3)

In the alternative, Plaintiffs argue that class certification of a medical monitoring class under 23(b)(3) is also appropriate, because certification of this claim is superior to other available methods for the fair and efficient adjudication of this claim and there are issues of fact and law that are common relating to research, testing, design, marketing and distribution of Baycol. As the individual issues undermine the cohesiveness of a (b)(2) certification, such individual issues also predominate over the common issues rendering class certification under (b)(3) inappropriate as well. In addition to the individual issues that arise in connection with the aspect of the medical monitoring claim involving negligence or strict liability, Plaintiffs' expert, Dr. Kaysen, pointed out that the risks of future injury vary depending on the amount and length of time during which Baycol was ingested. Thus, the potential for future injury can only be decided by looking to the individual medical histories of the class members.

III. Refund Class

Plaintiffs also seek to certify a refund class under subdivision (b)(3) and (c)(4). The refund class seeks restitution, disgorgement of profits and punitive damages based on claims of unjust enrichment and breach of implied warranty of merchantability and breach of warranty against redhibitory defects (under Louisiana law).

The named class representatives are: 1) James Henry Broadway, - a Louisiana resident who took .4 mg per day from November 1999 through August 2001; 2) Joan Dobrowits, an Illinois resident who took .4 mg per day from July 2001 through August 2001; and Marsha Miller, who is also a member of the medical monitoring class.

Given the relatively small size of the individual claims within this class, Plaintiffs argue that certification is necessary to ensure that the class members are able to have their day in court. They further argue that certification is warranted, as this class meets the requirements of Rule 23(a) and (b)(3). The Court does not agree.

With respect to both the unjust enrichment and breach of warranty claims, Plaintiffs argue that common issues predominate because the main thrust of these claims focus on Defendants' conduct. To prove the unjust enrichment claim, Plaintiffs need only show that Plaintiffs paid the Defendants, Defendants accepted the payment and that it would be unjust for Defendants not to return the payment. Thus, to prove unjust enrichment, Plaintiffs need not show that they did not benefit from Baycol, rather the focus is on Defendants' conduct. Plaintiffs further argue that to prove the breach of warranty claim, Plaintiffs must prove that Baycol is not fit for its ordinary purpose of reducing cholesterol because it is not an effective cholesterol-reducing drug and it is unreasonably dangerous.

The Court cannot accept this argument, however, for it is based on the premise that Baycol did not provide any benefit. This premise, however, is not supported by Plaintiffs' own expert, Dr. Kaysen. Dr. Kaysen was asked at his deposition whether he believed Baycol effectively reduces cholesterol in patients, to which he replied "Yes."

Kaysen Dep., p. 19. He further stated that "[Baycol] was an effective drug with regard to reducing cardiovascular risk" and admitted that the vast majority of individuals who took Baycol suffered no injury from Baycol. Id. p. 30. He also stated "Cerivistatin is a drug that does lower cholesterol, does reduce inflammation, and when it was marketed, it was a useful drug for reducing cardiovascular risk." Id. p. 32. He further agreed that to determine whether a patient received their money's worth from Baycol, "[o]ne would have to know whether or not they suffered any injury to be able to tell that completely." Id. p. 33.

Contrary to Plaintiffs' argument, to succeed on either the unjust enrichment or breach of warranty claims, Plaintiffs would have to demonstrate that they were either injured by Baycol, or that Baycol did not provide them any health benefits. See In re Rezulin, 210 F.R.D. at 61; accord Clay v. The American Tobacco Company, 188 F.R.D. 483, 501 (S.D. Ill. 1999)(individual inquiry bears directly on liability for unjust enrichment). Individual issues predominate, rendering class certification unwarranted.

As with the personal injury and medical monitoring classes, application of the state law in which the class member resides will likely govern the unjust enrichment and breach of warranty claims. Plaintiffs argue that this will not impose a barrier to class certification, because the laws of both unjust enrichment and breach of warranty are generally uniform and without material variation.

In an attempt to show that the laws regarding unjust enrichment and breach of warranty are generally uniform, Plaintiffs have provided the Court a survey of the state's laws. The survey concerning unjust enrichment identifies whether a particular state

recognizes an unjust enrichment claim when a defendant engages in inequitable or wrongful conduct, and whether principles of equity provide for restitution or disgorgement as a remedy for unjust enrichment. Plaintiffs Ex. F. However, a more extensive analysis of the law may be necessary. For example, in Clay supra, the court held that "variances exist in state common laws of unjust enrichment. The actual definition of "unjust enrichment" varies from state to state. Some states do not specify the misconduct necessary to proceed, while others require that the misconduct include dishonesty or fraud." Id., 188 F.R.D. at 501 (citations omitted). Another variance identified by Defendants is that some states consider unjust enrichment a remedy at law, Partipilo v. Hallman, 510 N.E.2d 8, 11 (Ill. App. Ct. 1987), while other states consider it an equitable claim. Southtown Plumbing, Inc. v. Har-Ned Lumber Co., 493 N.W.2d 137, 140 (Minn. Ct. App. 1992).

With respect to the breach of warranty claims, Plaintiffs' survey of the state laws focuses on whether privity is a requirement or not. Plaintiffs Ex. F. Other courts, however, have either expressed doubt that state warranty laws are not materially different, or have held such differences preclude nationwide certification of such claims. See, In re Rezulin, 210 F.R.D. at 71 (differences in state laws preclude class certification); In re: PPA Products Liability Litig., MDL No. 1407, slip op. at 7-17 (W.D. Wash. Sept. 4, 2002)(Defendants Ex. 29)(plaintiffs failed to meet their burden of demonstrating that differences in state law are neither significant or material); Walsh v Ford Motor Co., 807 F.2d 1000, 1016-1017 (D.C. Cir. 1986) cert. denied, 482 U.S. 915 (1987)(finding plaintiffs have not met their burden of showing state warranty laws were

uniform, and noting "The Uniform Commercial Code is not uniform)(citing, J. White & Summers, Uniform Commercial Code 7 (2d ed. 1980)).

This Court finds that Plaintiffs have not provided the Court sufficient information for it to conclude that the laws concerning unjust enrichment and breach of warranty are not significantly or materially different. Plaintiffs have thus failed to demonstrate that common issues of law predominate.

Finally, Plaintiffs concede that some states impose a privity requirement with respect to breach of warranty claims, and suggest that individuals from states with a privity requirement would be considered as not asserting a breach of warranty claim. Plaintiffs' Supplemental Brief, p. 11. However, two of the three named representatives, Ms. Miller, an Ohio resident, and Ms. Dobrowits, an Illinois resident, are subject to the privity defense. See Ohio Dept. of Admins. Servs. v. Robert P. Madison Inc., 741 N.E.2d 551, 556 (Ohio 2000); Szajna v. General Motors Corp., 503 N.E.2d 760, 766 (Ill. App. Ct. 1987). Accordingly, they cannot adequately represent those absent class members who are asserting a breach of warranty claim. The remaining class representative, Mr. Broadway, is a resident of Louisiana, which is governed by Louisiana's redhibition provision. He is thus not an adequate or typical representative of those class members from the remaining states.

IV. Punitive Damages

Finally, Plaintiffs argue that the issue of Defendants' punitive conduct is appropriate for certification. Plaintiffs propose that a class wide trial on punitive conduct be held and the jury asked whether Bayer provided false information to the

FDA, concealed adverse events reports etc. These findings could then be used in the individual class members' trials. In re: Simon II Litig., 211 F.R.D. 86 (E.D.N.Y. 2002). However, as is the case with the personal injury, medical monitoring and refund claims, individual issues of fact and law predominate with respect to punitive damages as well.

To succeed on a punitive damages claim, a plaintiff must prove that the defendant's conduct toward him/her rises to the level required by law. TXO Productions Corp. v. Alliance Resources Corp., 509 U.S. 443 (1993). See also, In re Telectronics, 172 F.R.D. at 294 (class certification of punitive damages not proper because, like compensatory damages, punitive damages measured individually based on the facts and local law); In re Copley Pharmaceutical, 161 F.R.D. at 467-468 (punitive damages are measured in part by how outrageous such punitive conduct is relative to a particular plaintiff.) As these cases clearly indicate, a determination of punitive damages is based on individual issues.

The Supreme Court's decision in State Farm Mutual Automobile Insurance Company v. Campbell, 123 S.Ct. 1513 (2003) further illustrates this point. First, the Court reiterated that the reasonableness of a punitive damages award must be based, in part, on the "disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award". Id. at 1520. Another factor relevant to the reasonableness of a punitive damages award is "the degree of reprehensibility of the defendant's misconduct." Id. With respect to this factor, the Court held that a punitive damages verdict cannot be based on conduct that bore no relation to the plaintiff's harm. Id. at 1523. "A defendant should be punished for the conduct that harmed the plaintiff,

not for being an unsavory individual or business. Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis. . . ". Id.

In this case, Plaintiffs' proposed class trial on punitive damages poses similar due process concerns because the conduct upon which Plaintiffs would base their punitive damages claim is not specific to a particular plaintiffs' claims. Rather, Plaintiffs propose that the jury make findings as to punitive conduct with respect to all actions taken up to the date Baycol was taken off the market. However, where liability is based on the Defendants' knowledge and conduct as of the date a particular plaintiff was prescribed Baycol, evidence supporting a punitive damages award must be similarly limited. Also, a plaintiff who allegedly suffered injury as a result of monotherapy use of a smaller dose of Baycol, should not recover punitive damages based on Defendants' knowledge and conduct with respect to the marketing of .8 mg, or the concomitant use of Baycol with gemfibrozil.

An additional barrier to class certification of a punitive damages claim is the multiple variations in the law of punitive damages among the states. As recognized by the court in In re Telectronics, the law of punitive damages among the states is varied; from the procedures utilized to impose punitive damages, to the conduct and proof necessary for the recovery of punitive damages. Id. 172 F.R.D. at 294. For example, in Minnesota, a claim for punitive damages must be proven by clear and convincing evidence, Minn. Stat. § 549.20(1)(a). In Idaho, however, the standard is by a

preponderance of the evidence, Idaho St. § 6-1604(1), while in Colorado, the standard is one of reasonable doubt. Col. St. § 13-25-127(2). With respect to prescription drugs approved by the FDA, some states prohibit the award of punitive damages. See eg., Ariz. St.§ 12-701(A); N.J. Pros. Liab. Act § 2A:58C-5(c); N.D. Code § 19-02.1-26(1); Ohio Code § 2307-80(c).

Plaintiffs have failed to demonstrate how the variations in state law can be managed in a class trial. Thus, Plaintiffs have failed to demonstrate that certification of the punitive damages claim is the superior method. See, In re Telectronics, 172 F.R.D. at 294.

IT IS HEREBY ORDERED that Plaintiffs' Motion for Class Certification is DENIED.

Date: September 17, 2003

_____//s//_____
Michael J. Davis
United States District Court